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DEPARTMENT OF HUMAN RESOURCES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

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Drug Use Review Board

Las Vegas Chamber of Commerce
6671 Las Vegas Blvd. S., Suite 300
Las Vegas, NV

Meeting Minutes
January 28, 2010

Committee members present:
Paul Oesterman, Pharm.D., Chairman
Keith Macdonald, R.Ph.
James Marx, MD

Absent:
David England, Pharm.D.
William Evans, MD
Steven Rubin, MD
Chris Shea, Pharm.D.

Others present:
Coleen Lawrence-DHCFP, Gabriel Lither-DAG, Rob Coppola-FHSC, Dave Wuest-FHSC, Adam Browning-FHSC, Paula Townsend-FHSC, Shirley Hunting-FHSC, Mike Crittenden-Wyeth, Steve Farmer-Amgen, Diana Khader-Pfizer, Chris Almeida-Purdue, Joe Hennessy-Purdue, Penny Atwood-Boehringer Ingelheim, Steve Nelson-Merck, Isam Herndon-GSK, Michelle Threole-J&J, Chase Freeman-Pfizer, Ozlem Eqvils-Pfizer, Daniel Bay-Abbott, Larry Gray-Pfizer, Jane Stephen-Allergan, Dana Conell-Novo Nordisk, Pat Wiseman-Medimmune, Ronnie DePue-Forest, Dave Powell-Forest, Chad Patel-Lilly, Helen Liao-Lilly, Larry Hinson-Astra Zeneca.

I. Call to Order and Roll Call

Chairman Paul Oesterman called the meeting to order at 1:04 p.m.

He reminded the public that public comment is limited to five minutes per individual, organization or agency.

Mr. Oesterman stated that a quorum of the Board members is not present therefore action items will be deferred to the next meeting.

II. Review and Approval of July 30, 2009, Meeting Minutes

Deferred until the next meeting.

III. Status Update by DHCFP

a. Introduction of New First Health Staff

Coleen Lawrence stated that First Health Services has new personnel on the pharmacy team and requested that they introduce themselves;

- Adam Browning, Pharm.D., will assume the role of Pharmacy Account Manager. His background has been in managed care most recently with Rx America.

- Paula Townsend, Pharm.D., has several years of experience in managed care most recently with Medco Health. Her role with First Health will be Pharmacy Clinical
  Account Manager.

- Rob Coppola, Pharm.D., MBA is a pharmacy director with First Health Services and assisting in the transition process with the training of the new staff and will be facilitating today's meeting. He's been with First Health for seven years. His prior experience includes many years as a pharmacy provider.

b. Program Updates

Coleen Lawrence reported that DHCFP is recruiting for the State's pharmacy program specialist position which is currently vacant.

IV. Review of Prescribing/Program Trends

a. Top 10 Therapeutic Classes (by Payment and by Claims)

Rob Coppola stated that there are a number of behavioral health medications within the Top 10 Classes Ranked by Payment Amount report. The highest ranked class by payment amount for fourth quarter 2009 was H7T (antipsychotics, atypical, dopamine, & serotonin antagonists) and is driven by the drug Abilify®. Analgesic narcotics (H3A) ranked second followed third by H7X (other antipsychotics). When benchmarked against other programs within First Health Medicaid clients, this is a common profile. He noted that in terms of cost, the insulins have been on the rise over the last few quarters. Regarding class Z4B (leukotriene receptor antagonists), most of the utilization falls under Singular®. The beta-adrenergic glucocorticoid combinations (J5D), Advair® and Symbicort®, are the only two drugs within the category and this class is within the top ten in utilization.

The Top 10 Therapeutic Classes Ranked by Claims Volume report captures more of the utilization of generic drugs. Analgesic narcotics (H3A) ranked number one which is consistent within all of First Health clients. The anticonvulsant class (H4B), ranked second, is led primarily by the third generation anticonvulsants which are primarily being used off-label and not necessarily as an anticonvulsant. The remaining therapeutic classes in the report are populated with behavioral health medications.

Dr. Marx asked if differentiation could be made within the anticonvulsant class as to whether utilization is for a diagnosis of epilepsy or other neuropathic pain.

Dr. Coppola replied that for the purpose of this report, diagnosis was not taken into consideration, but a report of pharmacy claims history against medical claims can be generated to determine diagnosis and presented at the next meeting. Mr. Wuest added that in order to run that report, some assumptions will have to be made due to cross-indications. He reiterated that some of the newer anticonvulsants do not have high utilization for epilepsy.

Dr. Marx felt that it's important to differentiate because the therapeutic paradigm is a little different. Rather than going to a third generation drug that might not be the most cost-effective, there may be a more appropriate therapy.

b. Top 50 Drugs (by Payment and by Claims)

Rob Coppola referred to the Top 50 Drugs Ranked by Payment Amount and noted that palivizumab (Synagis®) is ranked third during this reporting period due to RSV season, which ends in March.

c. Program Trends

Rob Coppola reported the recipient enrollment in January, 2009, was 73,800 members; year end enrollment closed at 79,500. He noted that September hit a high point of over 80,000 members. Utilizers of pharmacy services were approximately 30,000 to 32,000 in the same population during that timeframe. Claims have increased from 104,000 in January, 2009, to 109,000 in December. Generic utilization continued to increase during the year from 71% in January to a high point in December of 74%.

Mr. Oesterman asked if the DAW-1 edit is in place. He felt that the edit may have a significant impact on generic utilization.

Dr. Coppola replied that the public hearing is scheduled for April with implementation to follow soon thereafter. He clarified that generic utilization is a measurement of the number of times a generic claim is seen in the total claims database. The DAW-1 will impact the generic substitution rate, which is a measurement of the times that a generic is available and is used. Once the DAW-1 edit is implemented, the generic rate should increase.

V. Prospective Drug Utilization Review (ProDUR)

a. Review of Q3 and Q4 2009

Rob Coppola stated that prospective drug utilization review is mandated by the federal government under OBRA '90, which includes prospective DUR (ProDUR), retrospective DUR (RetroDUR), and concurrent DUR. DHCFP has selected eight pharmacy edits which are in place to assist the pharmacist with their ProDUR review. Dr. Coppola presented the ProDUR Message Reports for Q3 and Q4 2009, and noted that with the exception of duplicate therapy, the Too Soon Clinical (refill too soon) edit is the most common. Early refills may be dispensed only when 80% of the prescription is used for non-controlled drugs and 90% for controlled drugs. Claims with Severity level 1 (Major) ProDUR conflict messages will deny and require the pharmacist to enter the appropriate Intervention and Outcome Codes to override the denial. Claims which meet the criteria for Severity levels 2 (Moderate) and 3 (Minor) will not deny. The ProDUR system will send a message alerting the pharmacist of a potential risk for levels 2 and 3.

Mr. Oesterman asked if there is data available on how many claims that denied for Too Soon Clinical and were filled at that time versus waiting until the 80% or 90% utilization date was met; particularly, how many controlled substance prescriptions are being filled at the 90% window.

Mr. Wuest said that a report of early refill overrides for controlled substances can be generated and presented to the Board at the next meeting.

Mr. Macdonald said that many recipients will offer to pay cash in order to obtain their prescription early. The pharmacy denies the early refill and offers to contact the physician. Patients will comment that the physician has told them to take more than originally prescribed. The amount of utilization will change; the patient requests an early refill and will generally pay cash for it.

Dr. Coppola stated that in reviewing this data for other clients, the override rate is usually higher for non-controlled substances; less with controlled substances. This is reflective of the great job done by pharmacists in monitoring the utilization of their patients' controlled substances (concurrent drug utilization review). If the data indicates a high level of override, the Board may want to consider a more aggressive stance and create criteria for prior authorization.

Dr. Marx stated that in his practice, calls are received both from patients and pharmacies when an override is needed. He felt that an override was the way to handle situations if a prescriber has instructed the patient to take more than was written for. He said that he is not comfortable with setting any threshold level in which there is an early refill,

particularly with controlled substances. It seems that early fill behavior is being reinforced. One override may be okay, but if it's on a consistent basis, there could be a problem. Patients are counting the days and once at 85% of the days supply dispensed, the prescription can be filled. This correlates to refills being granted on day twenty-three and the prescriptions are being filled every three weeks instead of every four weeks.

VI. Retrospective Drug Utilization Review (RetroDUR)

a. Review of Responses (Q2 2009)

Rob Coppola stated that, historically, First Health has used their consultants in Richmond to drive what clinical criteria are selected for review and the local staff has done a great job of marrying RetroDUR up with initiatives being done in the State. For instance, a recommendation which may be brought forward is a retrospective review of Suboxone® utilization which will marry up with any decision made by the Board based on the proposal for prior authorizations. Moving forward, the Board will be asked to recommend what criteria to be run in order to meet the federal RetroDUR program requirements.

b. Status of Previous Quarter (Q3 2009)

Dr. Coppola reviewed the RetroDUR Letter Response Report by Response Code for the third quarter of 2009. The report includes responses for both new reviews and re-reviews. For April, 2009, 301 letters were sent with 62 responses received for a response rate of 21% which is considered a high percentage. Typically, response rates across FHSC clients is 20% and below. The response rate for May was 16% and 14% for June. He noted that based on the responses, the majority of prescribers did not make modifications to therapy based on the information provided; most felt the information was useful.

Mr. Wuest stated that the Board will be asked to participate in selecting criteria for new reviews. Re-reviews are profiles from the original profile run which again meet the criteria six months later. The prescriber may be re-lettered on re-review profiles. Both new and re-review profiles go through clinical review by a pharmacist to determine if a letter is warranted.

Dr. Marx expressed concern regarding the low percentage of responses to the June review of acetaminophen greater than 4 grams/day. As he indicated in a prior meeting, he felt 4 grams is excessive and that anything over 2.5 grams is excessive. It appears that there was little change in behavior based on the letters.

Dr. Coppola responded that in the two previous months, of the profiles pulled, a high percentage of letters were sent (301 in April; 261 in May). Of the 300 profiles reviewed in June, there were only 123 that met the consultant pharmacist's criteria for lettering the prescriber.

Mr. Wuest stated that there have been previous profile runs for the acetaminophen criteria. This criteria was selected again in June based on the Board's recent action to edit claims for acetaminophen greater than 4 grams/day. The low response rate may be due to back-to-back runs.

Mr. Macdonald asked if prescribers write in negative comments and/or request that they no longer receive future letters. Mr. Wuest replied occasionally that does occur but overall, the responses are positive.

Ms. Lawrence said that it may be helpful to know the trend of how many letters were sent for the first review, the re-review, and determine if the number of letters is decreasing and/or if there is any change in the prescribing physician or prescribing behavior.

Mr. Wuest responded that a report can be generated by prescriber and by patients that hit that list and compare it to what happened subsequent to implementation of the edit.

Mr. Oesterman stated that a lot of time and effort goes into the review and sending of the letters. Of those prescribers that respond, there is a large number that indicate that the information has been reviewed and will continue without change. Is there a better approach on how to intercede on these?

Mr. Wuest responded that one alternative is academic detailing which is becoming the trend. He noted that since the implementation of NPI, the response rate has doubled as the "dummy" prescriber number is no longer accepted by the pharmacy system.

Dr. Coppola distributed examples of RetroDUR letters to the Board.

c. Status of Current Quarter (Q4 2009)

Rob Coppola reviewed the RetroDUR summary reports for Q3 and Q4 2009 for new reviews and re-review profiles. The report includes the criteria selected for each month, the number of profiles generated and lettered, and the number of physicians impacted. The data for these two quarters is still being collected. A report on Q3 will be presented at the next meeting.

Dr. Coppola stated that retrospective review can be done on pharmacies as well. Mr. Oesterman stated that information on pharmacy performance in terms of early refills and those that have a higher rate of drug utilization review issues would be good information and for use as a learning tool to share with pharmacies. Mr. Wuest said a report will be generated for Board review.

d. Selection of Quarter Criteria (Q1 2010)

Rob Coppola said that the Board will be asked to review information provided by DHCFP and FHSC as well as draw upon their own experience with current literature and emerging trends to identify and develop criteria for profiles to be reviewed retrospectively.

Paul Oesterman reminded the Board and public that due to the lack of a quorum, decisions cannot be made by the Board today. This will be an open discussion.

Ms. Lawrence clarified that currently, DHCFP and FHSC make the decision on which criteria will be used for each month's RetroDUR profile run. For future profile runs, the Board is being asked to provide recommendations for criteria to review. She suggested a review of antipsychotic utilization in children before and after implementation of the prior authorization requirement and to tie in education with the enforcement of this policy.

Gabriel Lither stated that a recommendation from the Board implies an action which is different from members saying individually what they think may be important versus an actual recommendation from the Board. A recommendation from the Board would best be considered under an actual vote.

Dr. Coppola said that FHSC will continue to work in collaboration with DHCFP in the selection of criteria through Q1 2010. He reviewed the criteria exception reports which include the clinical criteria currently used to identify the recipients whose profiles are generated and used to select the prescribers that are lettered. The reports rank criteria by payment amount, number of claims and number of exceptions.

DHCFP and FHSC are recommending the following retrospective profile runs

1. Suboxone® use with opioid analgesics. These agents aren't typically used together yet there are approximately one-hundred recipients identified in the exception report within the three month reporting period.

2. FDA alert on the potential hazard of using skin numbing products containing topical anesthetics. This is recommended to support the recent action taken by the Board on Lidoderm® patches.

3. Cyclobenzaprine duration of therapy greater than three weeks is also recommended. This run ties in with a recent Pharmacy & Therapeutics Committee (P&T) decision that was implemented by DHCFP.

When selecting criteria from the exception reports, the number of exceptions (profiles) should be considered in order to meet the requirement of 300 profile reviews per month. The thought process when selecting criteria is to consider what might be a current issue in the state, such as behavioral health. Duplicate therapy (duplicate narcotic therapy, duplicate atypical therapy, antipsychotic therapy) and polypharmacy are also often reviewed and yield excellent results. Prescribers will receive letters with patient profiles and may become aware of other prescribers writing opiate therapy, as an example, for their patients. Many prescriber responses will indicate that this type of information is very useful and request that this type of information be sent more often.

Mr. Wuest reiterated that these profile hits may seem broad but recommendations are made by the pharmacist reviewer based on office visits, labs, etc. Dr. Coppola added that the profiles contain not only prescription drug history, but also the medical history (doctor's visits, ER visits, lab work, etc.). The same information contained in the profiles is included with the letter sent to the prescriber.

Dr. Coppola stated that the profile runs for Q1 2010 will include the criteria as recommended by DHCFP and FHSC above. At the next meeting, FHSC will present to the Board recommendations for Q2 2010 criteria review. The Board is also encouraged to recommend criteria for review at the next meeting.

e. Discussion by Board

Mr. Oesterman requested a review of medications which may increase the risk of falls in the elderly. He asked in terms of opiates and controlled substances if there is a way to interface with the Narcotic Task Force data.

Ms. Lawrence replied yes that currently there is an interface with the task force through the board of pharmacy and the DHCFP lock-in program.

Dr. Coppola also recommended non-compliance with therapy reviews be considered; e.g., non-compliance with SSRIs, non-compliance with hypertension medications, etc. This provides the prescriber with information on how compliant their patients are with their medications aiding them in their treatment design decisions.

Mr. Macdonald asked if non-compliance is overuse. Dr. Coppola replied that non-compliance includes both over *and* under use of medications (consistent months of not filling and/or greater than five days between fills).

Ms. Lawrence suggested that the parameters for polypharmacy and under and overuse of medications be provided to the Board. Dr. Coppola stated that the parameters are configurable and can change and will provide to the Board what is typically run. Mr. Wuest added that simple modifications can be made to the parameters.

f. Public Comment

No comment.

VII. Update by First Health Services on the Utilization of Psychotropic Medications in Children and Adolescents

a. Public Comment

No comment.

b. Discussion by Board

Rob Coppola stated that the Board approved clinical criteria for psychotropic medications in children and adolescents at the October, 2008, meeting and implementation of the criteria was April 15, 2009. A claims review was conducted to determine the effectiveness of the intervention. For the 0-5 age group, there was a move towards more appropriate utilization; age group 6-13, there was no change; age group 14-16, there was an increase in utilization.

Ms. Lawrence clarified that the age groups in policy are 0-5 years of age and 6-17 years of age. In the 0-5 year group, justification is required in order to prescribe more than one medication from the same class. Findings indicated that there has been a significant decrease in polypharmacy for this age group since implementation of the PA requirement. For the 6-17 year age group, there was data collection (indication, diagnosis) only and no denial of claims.

Dr. Coppola added that the steps currently being taken are to review submitted data and present findings to the Board to reevaluate for potential further action.

VIII. Update by First Health Services on Dispense as Written (DAW-1) Edit

a. Public Comment

No comment.

b. Discussion by Board

Rob Coppola stated that the Board approved the DAW-1 edit at the July, 2009, meeting. It will be presented at public hearing in April, 2010, and implemented soon thereafter. Claims submitted with a DAW-1 will reject and require prior authorization. The criteria developed at the July meeting will be used to determine approvals and denials.

IX. Update by First Health Services on Acetaminophen Accumulation Edit

a. Public Comment

No comment.

b. Discussion by Board

Rob Coppola stated that this edit was approved by the Board at the April, 2009, meeting and was implemented on October 15, 2009. Today's update was to report on the impact of the edit, but there was not sufficient data available. FHSC's staff biostatistician recommends a minimum of six months of data be aggregated in order to conduct a meaningful analysis. A report will be presented at the next meeting, if possible.

X. Review of Existing Fibromyalgia Prior Approval Criteria

Paul Oesterman invited public comment on action items but because a quorum of the Board is not in attendance, Board discussion and action will not be provided today. Public comment offered on action items today will have to be repeated at the next meeting.

Mr. Lither added that the public can comment on this or on any item under XIV but the Board cannot deliberate or take any action today. When the Board does come forward with this information in the future, information will have to be re-presented.

a. Public Comment

Ronnie DePue, Pharm D. Forest Research Institute, spoke in support of Savella® (milnacipran) for the management of fibromyalgia. Milnacipran is a 5HT norepinephrine reuptake inhibitor (SNRI). Peer reviewed publications and a recent meta-analysis have shown that SSRIs and tricyclic antidepressants (TCA) have limited clinical benefit in fibromyalgia. SNRIs show increased clinical efficacy and emerging animal evidence suggests that SNRIs, with a preference for norepinephrine reuptake, may actually play a more important role in chronic pain states. Milnacipran is reported to inhibit norepinephrine reuptake with an approximate threefold potency over serotonin and does not significantly inhibit other receptors or ion channels. Milnacipran has a high oral bioavailability of 85%, demonstrates a half-life of 8-10 hours and exhibits linear kinetics. Milnacipran absorption is not altered by food, has 13% protein binding and is primarily excreted through the kidneys. This is important as fibromyalgia patients are typically on multiple medications. Two pivotal trials of six and three months in duration with a combined total of over 2,000 patients, compared 100mg and 200mg milnacipran to placebo in a double-blind fashion. These two trials incorporated recommendations formulated by physicians whose goal was to identify and rank the chief symptoms using a composite responder approach. Milnacipran is safe, well tolerated and weight neutral. Milnacipran has a class label warning for suicidality and serotonin syndrome. Milnacipran demonstrates simultaneous and significant improvement in three key outcomes associated with fibromyalgia, has a negligible and manageable side effect profile and appears to offer a number of additional unique treatment attributes in comparison to other FDA approved and non-FDA approved agents.

Dr. Marx asked if there are head-to-head studies with other products that are indicated for fibromyalgia. Dr. DePue replied that currently, there are no head-to-head studies. Dr. Coppola asked if there are head-to-head studies with TCAs and if the meta-analysis mentioned was based on indirect comparisons only. Dr. DePue replied that the studies with milnacipran were placebo controlled. The meta-analysis was a systematic review of the literature looking at clinical trials using TCAs for the management of fibromyalgia. It was not noted that there was a durability of response with the TCAs. Durability and response was not demonstrated beyond eight weeks or in doses above 25mg. Most were short-term trials up to twelve weeks. It was concluded that more studies are needed before it can be said that there is drug durability of response whereas with milnacipran, there is six month and one year data.

Chad Patel, Lilly Health Outcomes, spoke in support of Cymbalta®. Cymbalta® has been on the market since 2004, has two mood-based indications and two pain conditions. He asked what the process is if a patient in Nevada has a prescription for Cymbalta® for depression or generalized anxiety disorder.

Dr. Coppola replied that the Preferred Drug List exception criteria would apply.

Mr. Patel commented that in terms of fibromyalgia, there is a high overlap in the literature of co-morbid mood and depression. Two-thirds of the patients also have associated types of depression, anxiety disorder within their patient histories. Clinical trial data with Cymbalta® showed differences in patients with both co-morbid mood disorders versus without within the clinical registration studies.

b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for Fibromyalgia Agents (Lyrica®, Savella® and Cymbalta®)

Deferred until the next meeting.

XI. Review of Existing Onychomycosis Prior Approval Criteria

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for Onychomycosis Agents (oral and topical)

Deferred until the next meeting.

XII. Proposed Prior Approval Criteria for Suboxone® and Subutex®

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for Suboxone® and Subutex®

Deferred until the next meeting.

XIII. Proposed Prior Approval Criteria for Zyvox®

a. Public Comment

Ozlem Eqvils, Pfizer, introduced herself and stated that she would provide no comment at this time.

b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for Zyvox®

Deferred until the next meeting.

XIV. Public Comment

No comment.

XV. Date and Location of Next Meeting

The next meeting is scheduled for April 22, 2010, at the Airport Plaza in Reno at 1:00 p.m. Dr. Marx and Mr. Oesterman stated that they have a conflict on that day.

XVI. Adjourn

Chairman Oesterman adjourned the meeting at 2:14 p.m.